

AppIn No 09/720.096

## REMARKS/ARGUMENTS

These Remarks are responsive to the Office Action mailed October 1, 2004 ("Office Action"). Claims 1, 9-14, 17, 24, and 28-32 are pending in the application. Claims 1, 11, 24, 28, 29, 30, and 31 are amended. Claims 26 and 27 are cancelled without prejudice. The amendments do not raise any issues of new matter. For example, support for the amendments is found at page 6, lines 26-28. Applicants respectfully request reconsideration of the rejections of claims 1, 9-14, 17, 24, and 28-32 for at least the following reasons.

### The Invention

The claimed invention relates to a novel and unobvious method of fermenting milk by means of a purine or thymidine auxotrophic bacterial culture which is capable of being metabolically active in said milk. The method comprises (i) isolating a purine or thymidine auxotrophic bacterial strain, (ii) propagating the isolated bacterial strain in a medium wherein the strain is capable of replicating to obtain a bacterial culture of said strain, (iii) adding the thus obtained bacterial culture to the milk and keeping the milk under conditions where the bacterial culture is able to acidify the milk, but is not capable of replication. According to the inventive method, if the milk is contaminated with a bacteriophage, the milk is acidified to a pH lower than milk acidified using a wild type parent strain of said purine or thymidine auxotrophic bacterial strain. *See, e.g.*, claim 1. The invention can be applied to, among other uses, manufacturing a milk product, dairy flavoring, and/or a product for cheese flavouring.

### Claim Objections

The Office Action objects to claim 24 as being grammatically incorrect in the recitation of "a milk" at line 3. Applicants have replaced "a milk" with "milk" as suggested in the Office Action. Applicants request withdrawal of the objection to claim 24.

The Office Action objects to claims 26 and 27 as being substantial duplicates of claim 1. While Applicants respectfully traverse this assertion, in the interest of expediting prosecution, they cancelled claims 26-27.

Appln. No. 09/720,096

**35 U.S.C. § 112, Second Paragraph**

Claims 1, 9-14, 17, 24, 26-27, and 30-32 were rejected under 35 U.S.C. § 112, second paragraph for being indefinite. The Office Action alleges that the phrase "conditions where the bacterial starter culture is metabolically active" is unclear. The term metabolically active has been replaced with "able to acidify milk." Applicants submit that the present claims are sufficiently clear to allow a person of ordinary skill in the art to ascertain what is claimed. Accordingly, the rejection of claims 1, 9-14, 17, 24, 26-27, and 31-32 for indefiniteness should be withdrawn.

Claim 11 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for lack of antecedent basis for the term "the material" at line 3. The term "material" is replaced with the term "milk," which has antecedent basis in the claim. Applicants submit that claim 11 is sufficiently clear to allow a person of ordinary skill in the art to ascertain what is claimed. Accordingly, the rejection of claim 11 for indefiniteness should be withdrawn.

Claims 28-29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for dependency on cancelled claims 4-5. Claims 28-29 have been amended to depend from claim 1. Applicants submit that claims 28-29 are sufficiently clear to allow a person of ordinary skill in the art to ascertain what is claimed. Accordingly, the rejection of claims 28-29 for indefiniteness should be withdrawn.

The Office Action alleges that claim 30 is "incomplete." Claim 30 states, among other elements, that "the bacterial culture is able to ferment the milk, but is not capable of DNA replication." Applicants submit that claim 30 is sufficiently clear to allow a person of ordinary skill in the art to ascertain what is claimed. Accordingly, the rejection of claim 30 for indefiniteness should be withdrawn.

The Office Action alleges that claim 31 is "confusing" because it is not clear whether the claim requires a "purine or thymidine auxotrophic bacterial strain." Claim 31 clearly requires a purine or thymidine auxotrophic bacterial strain. Applicants submit that claim 31 is sufficiently clear to allow a person of ordinary skill in the art to ascertain what is claimed. Accordingly, the rejection of claim 31 for indefiniteness should be withdrawn.

Appln. No. 09/720,096

**35 U.S.C. § 112, First Paragraph, Written Description**

The Office Action rejects claims 12-14 and 17 under 35 U.S.C. § 112, first paragraph, for failure to comply with the written description requirement. This ground of rejection appearing at pages 5-6 of the Office Action refers to paragraph [10] of the Office Action mailed May 4, 2004. Paragraph [10] of the office action mailed May 4, 2004 in turn refers to paragraph [10] of the Office Action mailed October 9, 2003. Applicants will respond to the rejection as it pertains to the rejected claims 12-14 and 17.

With respect to claims 12-14, the Office Action asserts that "the specification fails to disclose even a single representative species of the genus of genetically modified strains enhanced in at least one metabolic pathway." Office Action, p 5. At the outset, Applicants respectfully traverse the assertion that the written description requirement is not satisfied unless Applicants disclose at least one representative species of the claimed germs. It is well established that the written description requirement can be satisfied by a variety of means, including identifying characteristics, *e.g.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or combination thereof.

The Examiner is directed to page 11, lines 20-30 of the specification, which describes how the metabolic activity can be enhanced, *e.g.*, through an enhanced glycolytic pathway and/or an enhanced flux through the pentose phosphate pathway, of non-proliferating strains such as purine or pyrimidine auxotrophic strains, *e.g.*, strain MBP71 disclosed in Example 2. In the specification there is also described that the flux through the glycolytic pathway of purine or pyrimidine auxotrophic strains can be stimulated by increasing the expression of ATPase activity, *i.e.*, an enhanced conversion of ATP to ADP, as exemplified in WO 98/10089. WO 98/10089 gives concrete examples of numerous organisms (*e.g.* *E. coli*, *L. lactis*, etc.) modified in at least one metabolic pathway (*e.g.*, by increasing the expression of ATPase activity). The specification makes clear that the purine or thymidine auxotrophic bacterial culture may also be enhanced in at least one metabolic pathway. A person of ordinary skill in the art at the time of the invention was made would have readily recognized by reading the specification (including the references discussed therein) that applicants were in possession of

Appl. No. 09/720,096

the full scope of the inventions of claims 12-14 at the time of the invention. Accordingly, the rejection of claims 12-14 under 35 U.S.C. § 112, first paragraph, for lack of written description must be withdrawn.

With respect to claim 17, the Office Action asserts that the specification fails to disclose a representative species of "bacterial strain that is capable of increasing cell size without mitosis." Office Action, p. 6. However, example 2 of the specification discloses *Lactococcus lactis* strain MBP71—a bacterial strain that is capable of increasing cell size without mitosis. The ability of MBP71 to grow without replication (i.e., mitosis) is discussed at length in Pedersen et al., "Increasing Acidification of Nonreplicating *Lactococcus lactis*  $\Delta$ thyA Mutants by Incorporating ATPase Activity," Applied and Environmental Microbiology, Nov. 2002, pp. 5249-5257. The Applicants' specification is in no way limited to MBP71 in that it generally discusses bacterial strains that are capable of increasing cell size without mitosis at page 12, lines 11-17. Based on a review of the specification, a person of ordinary skill in the art would have recognized that applicants were in possession of the full scope of the invention of claim 17 at the time of the invention. Thus, the rejection of claim 17 under 35 U.S.C. § 112, first paragraph, for lack of written description must be withdrawn.

### 35 U.S.C. § 112, First Paragraph, Enablement

The Office Action rejects claims 1, 9-14, 17, and 24-32 under 35 U.S.C. § 112, first paragraph, as lacking enablement for "the methods as broadly encompassed by claims 1, 9-14, 17, and 24-32." In the section concluding that "[t]he claims are overly broad in scope," the Office Action contends that the disclosure is limited to "a method of fermenting milk . . . wherein if the milk is contaminated with a bacteriophage, the milk is acidified to a pH lower than milk acidified using a corresponding protrophic bacterial strain." Office Action, page 8. Applicants respectfully traverse this assertion and maintain that the claims, prior to their amendment herein, were fully enabled by the specification, at least because the specification (including examples) would enable skilled artisans to practice the full scope of the claimed invention as discussed in detail throughout prosecution of this application, e.g., in the Amendment filed March 9, 2004 incorporated herein by reference. In the interest of expediting prosecution, Applicants have amended their claims. Claim 1 now reads "whereby, if the milk is

Appln. No. 09/720,096

contaminated with a bacteriophage, the milk is acidified to a pH lower than milk acidified using a wild type parent strain of said purine or thymidine auxotrophic bacterial strain." Applicants submit that the present claims 1, 9-14, 17, and 24-32 are fully enabled under 35 U.S.C. § 112, first paragraph. Accordingly, the rejection of claims 1, 9-14, 17, and 24-32 under 35 U.S.C. § 112, first paragraph for lack of enablement should be withdrawn.

Applicants submit that this response addresses all of the issues raised in the Office Action. Applicants further submit that claims 1, 9-14, 17, 24, and 28-32 are in condition for allowance and notice to that effect is hereby solicited. Should any issues remain to be discussed in this application, the Examiner is invited to contact the undersigned by telephone.

Appln. No. 09/720,096

In the event any variance exists between the amount authorized to be charge to the Deposit Account and the Patent Office charges for reconsideration of this application, please charge or credit any difference to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,  
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